What’s changed in ISO 13485:2016?

Dr Arthur Brandwood

- Previous Director Devices Registration and Assessment at TGA and Director, TGA Biomaterials and Engineering Laboratories
- Past Chair National Board and Regulatory Expert Panel – AusMedtech
- Adviser to AHWP SG1 and Leader of Combination Products Task group
- Adviser and trainer to multiple Asia Pacific regional regulators
- Australian Delegation Leader to ISO TC 194 – Biocompatibility and Clinical Trials and ISO TC 150 – Implantable Devices
- Past President Australian Society for Biomaterials
- Visiting Professor in Biomedical Engineering, University of Sydney
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It’s Arrived!

- Published 1 March 2016
- 3 Year Transition Period. Expect:
  - all certifications after March 2018 to be to the new version
  - ISO 13485:2003 Certificates not valid after March 2019

  *(ISO/TC 210/WG 1 N 233)*

- Europe expected to harmonise and follow ISO transition...

http://www.iso.org/iso/catalogue_detail?csnumber=59752

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How to separate ISO 9001 and 13485?
Key Changes

- Emphasis on Regulations
- Risk
- Software
- Sterile Devices
- Complaints and Postmarket
- Departure from ISO 9001

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Three little words...

- ISO 9001
  Quality management systems — Requirements

- ISO 13485
  Medical devices — Quality management systems — Requirements for regulatory purposes

And now 3 more...

Product Safety and Performance
Emphasis on Regulatory Requirements

Objectives
- Product requirements
- Regulatory requirements

Regulatory Documents
- Technical File
- Complaint Files
- Design History File

Postmarket
- Reporting to regulatory authorities

Clause 8.5.1 Improvement
- Continued safety and performance (State of the Art?)
- Specific use of post market surveillance.
Risk

- Apply risk management to all processes, **including outsourced** processes
  - *Process Control*
  - *Purchasing*
  - *Software Validation*
- Use definition of Risk from ISO 14971
  - *This is different to the definition used in ISO 9001*
Risk

4.1.2 The organization shall:

a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization

b) apply a risk based approach to the control of the appropriate processes...
Risk

7.4.1 Purchasing process

...

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

...

d) proportionate to the risk associated with the medical device
Software

Consistent requirements for software validation

- QMS software
- Process control software
- Software for monitoring and measurement
The organization shall document procedures for the validation of the application of computer software used in the Quality Management System.
7.5.7  Particular Requirements for validation of processes for sterilization and sterile barrier systems

The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems.

NOTE Further information can be found in ISO 11607-1 and ISO 11607-2.
Sterile Devices

6.4.2 Contamination Control

For sterile medical devices, the organization shall document requirements for control of contamination with micro-organisms or particulate matter.
Complaints and Postmarket

8.2.2 Complaint handling

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for

a) receiving and recording information,

b) evaluating information to determine if the feedback constitutes a complaint,

c) investigating complaints,

d) determining the need to report the information to the appropriate regulatory authorities,

e) handling of complaint-related product, and

f) determining the need to initiate corrections or corrective actions.
Complaints and Postmarket

- Identify and implement changes necessary to maintain the system as well as ensure **continued** medical device **safety and performance**
- Includes specific requirements for post market surveillance
- Embodies concept of “state-of-the-art”

8.5.1 Improvement
A Fork in the Road...

ISO 9001:2015
1. Scope
2. Normative References
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

ISO 13485:2016
1. Scope
2. Normative References
3. Terms and definitions
4. Quality Management System
5. Management
6. Resource management
7. Product realization
8. Measurement, analysis and improvement

This is unchanged from ISO 13485:2003
But Wait, There’s More…

- Application throughout the lifecycle and supply chain
- Flexibility to exclude requirements in Clauses 6, 7, or 8
- Emphasis on appropriate infrastructure
- More detail in Design and Development: usability, use of standards, planning, transfer, records

- Statistics: Rationale for sample size, documented in plans
- Records: consider privacy regulations for protecting confidential health information
- User Training: verify that regulatory requirements will be met and user training will be available
Table A1 outlines the changes in this edition of this International Standard compared with the previous edition (ISO 13485:2003)
MDSAP
Medical Device Single Audit Program
Uses ISO 13485

USA
From 2017

Brazil
Ready Now

Australia
Ready Now?

Japan
Will take time...

Canada
Replace CMDCAS by 2019 (follow ISO Transition)
Full Day Training Seminar
9 May 2016
Adelaide, South Australia

http://brandwoodbiomedical.com/events/full-day-workshop-transition-to-iso-134852016

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